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Cardiovascular Systems

K132811

FEB 2 7 2014

510(K) SUMMARY
Sarns™ Soft-Flow® Extended Aortic Cannula

Date Prepared: August 2013

Sponsor Information:

Owner/Applicant/Submitter: Terumo Cardiovascular Systems Corporation
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Ann Arbor, Michigan 48103
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Corporate Director, Regulatory Affairs
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Device Names/Classifications:

Device Trade Name:	Sarns™ Soft-Flow® Extended Aortic Cannula
Device Common Name:	Aortic cannula for cardiopulmonary bypass
Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, tubing
Regulation Number:	21 CFR 870.4210
Classification:	Class II
Product Code:	DWF

Predicate Devices:

- Sarns™ Low Jetting Aortic Arch Cannula, K934127
- Sarns™ Xcoated Cannula, K083301

Device Description:

The Sarns™ Soft-Flow® Extended Aortic Cannula provides a conduit for the flow of patient blood within the extracorporeal circuit during cardiopulmonary bypass surgery. The design of the Sarns™ Soft-Flow® Extended Aortic Cannula allows patient blood to re-enter the body after the blood has routed through an extracorporeal circuit for blood oxygenation. The cannula consists of a tubular conduit with a tip that can be positioned into the patient's anatomy (ascending aorta) to allow the blood to re-enter the vascular blood stream.

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Intended Use/Indications for Use:
The Sarns™ Soft-Flow® Extended Aortic Cannula is indicated for perfusion of the ascending aorta during cardiopulmonary bypass surgery for up to 6 hours of use.

Performance Evaluations:
Clinical studies involving patients are not necessary to demonstrate the safety and effectiveness of the subject devices. Performance assessments for safety and effectiveness were accomplished through bench studies that included the following evaluations:

- force at break
- liquid and air leak
- ink adhesion
- hemolysis
- pressure drop
- exit velocity

Substantial Equivalence Comparison:
The information presented in this section depicts a comparison between the subject device, the modified Sarns™ Soft-Flow® Aortic Extended Cannula and the predicate device:

- Sarns™ Low Jetting Aortic Arch Cannula, K934127
- Sarns™ Xcoated Cannula, K083301

- ***Comparison of Intended Use:***
  The modified Sarns™ Soft-Flow® Extended Aortic Cannula and the predicate have the exact same intended use statements:

  > The modified and the unmodified devices are each indicated for perfusion of the ascending aorta during cardiopulmonary bypass surgery for up to 6 hours of use.

- ***Duration of Use:***
  The modified Sarns™ Soft-Flow® Extended Aortic Cannula and the predicate can both be used in procedures lasting up to 6 hours in duration.

- ***Comparison of Labeling:***
  The labeling used for the modified device is similar to the labeling used with the predicate device, although some labeling is revised to provide greater clarity for the user. The revised instructions labeling accurately presents the directions that are necessary for the end-user to employ the device in a safe and effective manner. Terumo submits that the labeling complies with applicable regulations in those regions where the device is to be distributed.

- ***Comparison of Operation and Technology:***
  The modified Sarns™ Soft-Flow® Extended Aortic Cannula and the predicate utilize the exact same technologies and principles of operation. The technology of the modified device is not impacted by the modifications made to the subject device.

- ***Comparison of Design:***
  With respect to the design of the modified Sarns™ Soft-Flow® Extended Aortic Cannula, changes to the device have been made since the original submission – each of which has been determined to maintain the integrity of the product without impacting the safety and effectiveness of the device.

- The Sarns™ Soft-Flow® Extended Cannula is 14.5 inches long, one-half inch longer than the 14 inch predicate device. This half inch difference in length is not clinically significant. Longer tubing allows clearance from and, thus improved visualization of, the surgical field, particularly in larger patients.

- The Sarns™ Soft-Flow® Extended Cannula has a positional suture ring and depth markings on the tubing. The positional suture ring and centimeter depth markings are used to gauge insertion depth of the cannula and provide a location to tighten the sutures around the cannula to hold it in place. These features are comparable in function to the predicate device which has a suture bulb to gauge insertion depth of the cannula and provide a location to tighten the sutures around the cannula to hold it in place.

- The Sarns™ Soft-Flow® Extended Cannula has a straight tip rather than an angled tip like the predicate devices. A straight tip design generally produces a slightly lower pressure drop (the difference between the pressure entering the cannula and the pressure leaving the cannula) compared to the same size angled tip. A lower pressure drop is desirable because there is less resistance to flow and thus less potential for hemolysis.

- The material that is used for the luer-threaded port cap is changed from polypropylene to ABS plastic. Terumo Cardiovascular Systems maintains a complete profile of all biocompatibility data that fully supports the suggested elements of FDA General Program Memorandum #G95-1: Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part I: Evaluation and Testing."

- ***Comparison of Materials:***
  The materials of construction used in the modified Sarns™ Soft-Flow® Extended Aortic Cannula are the same generic materials that are used in the predicate device with the exception of a cap material change from polypropylene to ABS plastic.

- ***Comparison of Performance:***
  Terumo Cardiovascular has conducted performance studies with the modified devices to ensure that they all continue to satisfy appropriate device performance specifications and to ensure that they satisfy customer needs. Specifically, performance studies were conducted to ensure force at break, liquid and air leak, hemolysis, pressure drop, exit velocity, ink adhesion, and biocompatibility testing passed pre-determined acceptance criteria. There are no appreciable differences in performance between the subject devices and the predicate devices. The nonclinical tests demonstrate the subject device is as safe and effective as the predicate devices.

Conclusion:
The information and data included in the 510(k) notice demonstrate the Sarns™ Soft-Flow® Extended Aortic Cannula is *substantially equivalent* to the predicate devices for perfusion of the ascending aorta during cardiopulmonary bypass for up to 6 hours of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 27, 2014

Terumo Cardiovascular Systems Corporation
Mr. Garry A. Courtney
Corporate Director, Regulatory Affairs
6200 Jackson Rd.
Ann Arbor, MI 48103

Re: K132811
Trade/Device Name: Sarns Soft-Flow Extended Aortic Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: January 29, 2014
Received: January 30, 2014

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 4 – INDICATION FOR USE
Sarns™ Soft-Flow® Extended Aortic Cannula

510(k) Number: K132811

Device Name: Sarns™ Soft-Flow® Extended Aortic Cannula

Indications for Use:
Device Intended Use - The device is indicated for perfusion of the ascending aorta during cardiopulmonary bypass surgery for up to six hours of use.

Prescription Use ____X____ or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)